

PHARMACY BOARD[657]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)“b.”

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under section 17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code sections 124.301 and 147.76, the Board of Pharmacy hereby gives Notice of Intended Action to rescind Chapter 11, “Drugs in Emergency Medical Service Programs,” Iowa Administrative Code, and to adopt new Chapter 11 with the same title.

The rules were approved at the April 29, 2010, regular meeting of the Board of Pharmacy.

The proposed rules define terms used throughout the chapter and establish responsibilities for parties involved in the provision of drugs to emergency medical service (EMS) programs. The amendments require a written agreement between the EMS program and the party or parties responsible for providing drugs to the EMS program and include procedures for termination of those services. The amendments address requirements for storage and security of drugs maintained at the EMS program site and require the development, implementation, and adherence to policies and procedures for the operation and management of the EMS program. Record-keeping requirements are established, methods for utilization and replenishment of drug stocks are defined, and special handling and record keeping relating to controlled substances are identified.

Requests for waiver or variance of the discretionary provisions of these rules will be considered pursuant to 657—Chapter 34.

Any interested person may present written comments, data, views, and arguments on the proposed rules not later than 4:30 p.m. on July 20, 2010. Such written materials may be sent to Terry Witkowski, Executive Officer, Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688; or by E-mail to terry.witkowski@iowa.gov.

These rules are intended to implement Iowa Code chapter 147 and Iowa Code sections 124.301 and 155A.13.

The following amendment is proposed.

Rescind 657—Chapter 11 and adopt the following **new** chapter in lieu thereof:

CHAPTER 11

DRUGS IN EMERGENCY MEDICAL SERVICE PROGRAMS

657—11.1(124,147A,155A) Definitions. For the purpose of this chapter, the following definitions shall apply:

“*Adulterated*” means any drug or device that consists in whole or in part of any filthy, putrid, or decomposed substance.

“*Ambulance service*” means any privately or publicly owned service program that utilizes ambulances in order to provide patient transportation and emergency medical services.

“*Authorized prescriber*” means any provider who has prescriptive authority in the state of Iowa.

“*Board*” means the board of pharmacy.

“*Bureau*” means the Iowa department of public health, bureau of emergency medical services (EMS).

“*CSA registration*” means a registration issued by the board pursuant to Iowa Code chapter 124, the Iowa controlled substance Act.

“*DEA*” means the U.S. Department of Justice, Drug Enforcement Administration.

“*DEA registration*” means a registration issued by the DEA pursuant to 21 CFR Part 1301.

“*Department*” means the Iowa department of public health.

“Drug” means a substance as defined in Iowa Code section 155A.3(13) or a device as defined in Iowa Code section 155A.3(10).

“Emergency medical care provider” means an individual who has been trained to provide emergency and nonemergency medical care at the first responder, EMT-basic, EMT-intermediate, EMT-paramedic, paramedic specialist, or other certification level recognized by the department before 1984 and who has been issued a certificate by the department.

“Emergency medical services” or *“EMS”* means an integrated medical care delivery system to provide emergency and nonemergency medical care at the scene or during out-of-hospital patient transportation in an ambulance.

“Emergency medical technician” means any emergency medical technician or EMT as defined in 641—132.1(147A).

“Medical direction” means direction, advice, or orders provided to emergency medical care personnel by a medical director, supervising physician, or physician designee (in accordance with written parameters and protocols).

“Medical director” means any physician licensed under Iowa Code chapter 148 who shall be responsible for overall medical direction of the service program and who has completed a medical director workshop, sponsored by the department, within one year of assuming duties.

“Medical director-based” means that ownership of the drugs maintained in and used by the service program remains with the medical director.

“Patient care report” or *“PCR”* means a computerized or written report that documents the assessment and management of the patient by the emergency care provider in the out-of-hospital setting.

“Pharmacy-based” means that ownership of the drugs maintained in and used by the service program remains with the pharmacy.

“Physician” means any individual licensed under Iowa Code chapter 148.

“Physician assistant” or *“PA”* means any individual licensed under Iowa Code chapter 148C.

“Physician designee” means any registered nurse licensed under Iowa Code chapter 152, or any physician assistant licensed under Iowa Code chapter 148C and approved by the board of physician assistant examiners. The physician designee acts as an intermediary for a supervising physician in accordance with written policies and protocols in directing the care provided by emergency medical care providers.

“Program site” or *“program location”* means the physical location from which the service program is operated.

“Protocols” means written direction and orders, consistent with the department’s standard of care, that are to be followed by an emergency medical care provider in emergency and nonemergency situations. Protocols shall be approved by the service program’s medical director and shall address the care of both adult and pediatric patients.

“Responsible individual” or *“RI,”* as this term relates to prescription drugs and devices in a medical director-based service, means the medical director for the service. In a pharmacy-based service, *“responsible individual”* means the pharmacist in charge of the base pharmacy.

“Service” or *“service program”* means any medical care ambulance service or nontransport service that has received authorization by the department.

“Service director” means the individual who is responsible for the operation and administration of a service program.

“Supervising physician” means any physician licensed under Iowa Code chapter 148 who supervises and is responsible for medical direction of emergency medical care personnel when such personnel are providing emergency medical care.

657—11.2(124,147A,155A) Responsibility. Pursuant to rules of the bureau, each service program shall appoint a service director at the program site.

11.2(1) Pharmacy-based. In a pharmacy-based service program, the pharmacist in charge shall be responsible for ensuring that the management of all prescription drugs and devices complies with federal and state laws and regulations. The pharmacist in charge shall not serve as the service director.

11.2(2) *Medical director-based.* In a medical director-based service program, the medical director shall be responsible for ensuring that the management of all prescription drugs and devices complies with federal and state laws and regulations.

11.2(3) *Combination pharmacy-based and medical director-based.* If both pharmacy-based and medical director-based programs are in effect, the pharmacist in charge of the base pharmacy and the medical director will be responsible for management of the drugs owned by the base pharmacy and by the medical director, respectively.

657—11.3(124,147A,155A) Written agreement. A signed written formal agreement for the service program shall be maintained at the service program site and be available for inspection and copying by the board or its representative.

11.3(1) *Pharmacy-based programs.* An Iowa-licensed pharmacy may enter into an agreement with a service program located in the state if the medical director of the service program has obtained a CSA registration as required by rule 657—11.6(124,147A,155A). The agreement with the service program shall establish that the service is operating as an extension of the base pharmacy with respect to prescription drugs and devices. The agreement shall be signed by the pharmacist in charge, the medical director of the service program, and the service director at the service program location. A copy of this agreement shall be maintained while in effect at both the pharmacy and the service program site.

11.3(2) *Medical director-based programs.* A service program shall maintain a formal written agreement with a medical director that is signed by the medical director and the service director. The agreement shall be maintained while it is in effect at the service program site.

657—11.4(124,147A,155A) Termination of services. EMS services may be terminated at the discretion of either the EMS program or the party or parties responsible for providing drugs to the EMS program. Written notification of such termination shall be provided to the other party at least 30 days prior to termination of services. Transfer of ownership of controlled substances shall be in compliance with rule 657—10.11(124).

11.4(1) *Pharmacy-based programs.* Immediately upon discontinuation of services, all controlled substances shall be jointly inventoried by the pharmacist in charge and the service director or their designees. A record of this inventory shall be maintained at the pharmacy for two years from the date of the inventory. All drugs and devices that are the property of the pharmacy shall be immediately returned to the pharmacy.

11.4(2) *Medical director-based programs.* Immediately upon discontinuation of services, all controlled substances shall be jointly inventoried by the medical director and the service director or their respective designees. A record of this inventory shall be maintained by the medical director for two years and be available for inspection and copying by the board or its representative. All drugs and devices that are the property of the medical director shall be immediately returned to the medical director.

657—11.5 Reserved.

657—11.6(124,147A,155A) Registration required. If the program is a medical director-based service program, the medical director shall obtain and maintain current CSA registration and DEA registration at the program location prior to commencement of responsibilities as medical director. Separate CSA and DEA registrations shall be obtained for each program location and shall be available for inspection and copying by the board or its representative and any other authorized agencies.

11.6(1) *Change of address of registered program location.* An individual practitioner may apply to change the address of the registered program location by submitting a request as provided in 657—subrule 10.11(2). The board and the DEA shall be notified in writing prior to a change of address of a registered program location.

11.6(2) *Change of medical director of a medical director-based program.* The board shall be notified in writing prior to the change of medical director. The new medical director shall obtain

a CSA registration and a DEA registration for the service program site prior to commencement of responsibilities as medical director.

657—11.7 Reserved.

657—11.8(124,147A,155A) Identification.

11.8(1) A log of employees who have access to prescription drugs and to records regarding procurement, storage, and administration of prescription drugs at the service program shall be maintained for two years and be available for inspection and copying by the board or its representative. This log shall include the employees' printed names and signatures, printed and signed initials, and their levels of certification.

11.8(2) Policies and procedures shall be developed, implemented, and adhered to that identify at least the following:

- a. Who has access to drugs.
- b. Who has authority to administer drugs.
- c. Who has authority to order, receive, and distribute prescription drugs and devices.

657—11.9 Reserved.

657—11.10(124,147A,155A) Ownership of prescription drugs and devices. All prescription drugs and devices obtained for use in a service program shall be owned either by a pharmacy or by the medical director of the service program.

11.10(1) *Pharmacy-based.* If the drugs are owned by the pharmacy, the service program shall be considered a pharmacy-based service program and shall comply with these rules as they pertain to a pharmacy-based service program.

11.10(2) *Medical director-based.* If the drugs and devices are owned by the medical director, the service program shall be considered a medical director-based service program and shall comply with these rules as they pertain to a medical director-based service program.

11.10(3) *Combination of pharmacy-based and medical director-based.* If the service program has entered into both pharmacy-based and medical director-based service program agreements, both the pharmacy and the medical director shall retain separate ownership of the supplied prescription drugs and devices and shall comply with these rules as applicable.

657—11.11(124,147A,155A) Policies and procedures.

11.11(1) Each service program site shall, jointly with the service director and the responsible individual, develop, implement, and adhere to written policies and procedures for the operation and management of the service program with respect to prescription drugs and devices. These policies and procedures shall be available for inspection and copying by the board or its representative. The policies and procedures shall be periodically reviewed by the responsible individual, the medical director, and the service director. Documentation of the review shall be maintained.

11.11(2) The policies and procedures shall address, at a minimum, the following:

- a. Storage of drugs at the service program site including appropriate temperature and humidity controls and security.
- b. Protocols for administration of drugs.
- c. Administration of drugs outside the parameters of written protocols.
- d. Record retention and format including:
 - (1) Ownership of drugs, devices, and medical supplies.
 - (2) Ordering of drugs, devices, and supplies.
 - (3) Receipt of drugs, devices, and supplies.
 - (4) Distribution or administration of drugs, devices, and supplies.
 - (5) Inspections of the service program site and equipment.
 - (6) Inventories of controlled substances.
 - (7) Wastage resulting from the administration of a partial dose or supply of a drug.

- (8) Drug, device, or supply returns.
- e. Process for the return of drugs.
- f. Out-of-date and adulterated drugs.
- g. Drug and device recalls.

657—11.12 Reserved.

657—11.13(124,147A,155A) Storage. Prescription drugs and devices at service program sites shall be stored in designated secure areas that are clean and free of debris, where temperature and humidity are appropriately controlled, and in a manner to protect identity and integrity.

11.13(1) Temperature. All drugs and devices shall be stored at the proper temperature. Drugs that are subjected to extreme temperatures shall not be administered to patients and shall be immediately removed from usable stock. Extreme temperatures shall be defined as excessive heat greater than 40 degrees Celsius (104 degrees Fahrenheit) and, if the product requires protection from freezing temperatures, excessive cold less than -10 degrees Celsius (13 degrees Fahrenheit). Disposal of unusable drugs shall be in compliance with rule 657—11.32(124,147A,155A).

11.13(2) Security. The security of prescription drugs and devices is the responsibility of the responsible individual. Policies and procedures for the security of prescription drugs shall provide for the effective control against theft of, diversion of, or unauthorized access to prescription drugs and devices, records for such drugs, and patient records. These policies and procedures shall indicate who has access to prescription drugs.

657—11.14(124,147A,155A) Protocols. Every service program shall utilize department protocols as the standard of care. The service program medical director may make changes to the department protocols provided the changes are within the EMS provider's scope of practice and within acceptable medical practice. Prescription drugs shall be administered pursuant only to a written protocol or oral order by an authorized prescriber. Records of current protocols shall be provided to and maintained by the responsible individual and the service director.

657—11.15(124,147A,155A) Administration of drugs beyond the limits of the written protocol. Drugs, excluding Schedule II controlled substances, may be administered beyond the limits of the written protocols provided that medical direction from an authorized prescriber has been obtained prior to administration. The authorization shall be recorded in the patient care report documenting the identity of the authorizing prescriber. If an agent of the authorized prescriber relayed the order, the identity of the prescriber's agent, including the agent's title, shall also be recorded.

657—11.16(124,147A,155A) Administration of Schedule II controlled substances. Schedule II controlled substances may be administered to patients under the care of a service program provided that a signed order is obtained from the authorized prescriber within seven days of the date administration was authorized.

11.16(1) Pharmacy-based. The original signed order shall be provided to the pharmacy. A copy of the signed order shall be maintained at the service program site for two years.

11.16(2) Medical director-based. The original signed order shall be retained at the service program site for two years and be available for inspection and copying by the board or its representative.

657—11.17 and 11.18 Reserved.

657—11.19(124,147A,155A) Patient care reports. Patient care reports shall be maintained at the service program site as required by the bureau and rule 657—11.34(124,147A,155A).

657—11.20(124,147A,155A) Prescription drugs and devices in EMS programs. Prescription drugs and devices maintained by a service program shall be owned by an Iowa-licensed pharmacy or the service program's medical director.

11.20(1) Pharmacy-based. The pharmacist in charge, medical director, and the service director shall jointly develop an inventory list of drugs and devices to be maintained for administration at the service program. The pharmacy shall maintain an accurate inventory of all prescription drugs and devices including controlled substances that the pharmacy maintains at the service program site.

a. Replenishment. The responsible individual, the service director, or designee may request that replenishment supplies of drugs be maintained at the service program site provided that the pharmacy has been supplied with administration records justifying the order. The pharmacist shall approve every drug taken from the pharmacy's dispensing stock that will be provided to the service program site prior to the transfer of the drug or device. Documentation of this verification shall be maintained within the pharmacy records.

b. Inspections. The pharmacist in charge shall ensure the completion of a monthly inspection of all prescription drugs and devices maintained by the pharmacy at the service program site. Inspection shall include the removal of outdated or damaged drugs. All drugs removed from administration stock at the service program site shall be returned to the pharmacy. Records of inspection shall be maintained for two years at the service program site and at the pharmacy. The pharmacist in charge may delegate the conduct of the monthly inspection to another pharmacist, a certified pharmacy technician, or the service director.

11.20(2) Medical director-based. The medical director and the service director shall jointly develop an inventory list of drugs and devices to be maintained for administration at the service program. The medical director shall maintain an accurate inventory of all prescription drugs and devices including controlled substances that the medical director maintains at the service program site. EMS personnel shall have authority to handle prescription drugs and devices pursuant to their scope of practice as defined by the bureau.

a. Replenishment. All drugs procured for administration in a medical director-based service program shall be obtained from an Iowa-licensed wholesaler, a pharmacy, or an authorized prescriber.

b. Inspections. The medical director shall ensure the completion of a monthly inspection of all prescription drugs and devices maintained by the medical director at the service program site. Inspection shall include the removal of outdated or adulterated drugs. Records of inspection shall be maintained for two years at the service program site. The medical director may designate EMS personnel to conduct required inspections.

657—11.21 Reserved.

657—11.22(124,147A,155A) Return of drugs. Drugs that have been removed from administration stock at the service program site shall be returned to the responsible individual. In a pharmacy-based service, drugs returned from the service program site to the base pharmacy may be used by the pharmacy for subsequent dispensing or administration provided the drugs are not outdated or adulterated. Records of the return of prescription drugs and devices shall be maintained by the responsible individual.

657—11.23(124,147A,155A) Out-of-date drugs or devices. Any drug or device bearing an expiration date shall not be administered beyond the expiration date of the drug or device. Outdated drugs or devices shall be removed from administration stock and quarantined until such drugs or devices are properly disposed of or, if the program is a pharmacy-based service, returned to the base pharmacy. Outdated drugs are the property of the responsible individual and shall be disposed of appropriately. Outdated controlled substances shall be disposed of pursuant to rule 657—11.32(124,147A,155A).

657—11.24(124,147A,155A) Product recall. All service programs shall have a system for removal from administration stock any prescription drugs and devices subject to a product recall. The system shall include action appropriate to the direction or requirements of the recall.

657—11.25 Reserved.

657—11.26(124,147A,155A) Controlled substances records.

11.26(1) *Records maintained.* Every inventory or other record required to be maintained under this chapter, 657—Chapter 10, or Iowa Code chapter 124 shall be maintained at the service program site and by the pharmacy if the service program is pharmacy-based. All required records shall be available for inspection and copying by the board or its representative for at least two years from the date of such inventory. Controlled substances records shall be maintained in a readily retrievable manner.

11.26(2) *Receipt and disbursement records.* Any pharmacy or other authorized registrant that provides controlled substances for a medical director-based service program shall maintain records of receipt and disbursement that include the following:

- a. The name of the substance;
- b. The strength and dosage form of the substance;
- c. The number of units or commercial containers acquired from other registrants, including the date of receipt and the name, address, and DEA registration number of the registrant from whom the substances were acquired;
- d. The number of units or commercial containers distributed to other registrants, including the date of distribution and the name, address, and DEA registration number of the registrant to whom the substances were distributed; and
- e. The number of units or commercial containers disposed of in any other manner, including the date and manner of disposal and the name, address, and DEA registration number of the registrant to whom the substances were distributed for disposal, if appropriate.

657—11.27(124,147A,155A) Ordering Schedule II controlled substances—medical director-based. Except as otherwise provided by 657—subrule 10.34(7) and under federal law, a DEA Form 222, preprinted with the address of the program location, is required to be maintained at the service program location for the acquisition of each supply of a Schedule II controlled substance. The order form shall be executed only by the medical director named on the order form or by an authorized signer designated pursuant to a properly executed power of attorney. A DEA Form 222 shall be dated and signed as of the date the order is submitted for filling. A medical director or authorized signer shall not pre-sign a DEA Form 222 for subsequent completion. All Schedule II order forms shall be maintained at the service program site and shall be available for inspection and copying by the board or its representative for a period of two years from the date of the record.

657—11.28 Reserved.

657—11.29(124,147A,155A) Schedule II perpetual inventory. Each service program located in Iowa that administers Schedule II controlled substances shall maintain a perpetual inventory for all Schedule II controlled substances pursuant to the requirements of this rule. All records relating to the perpetual inventory shall be maintained at the service program location and shall be available for inspection and copying by the board or its representative for a period of two years from the date of the record.

11.29(1) *Record.* The perpetual inventory record may be maintained in a manual or an electronic record format. Any electronic record shall provide for hard-copy printout of all transactions recorded in the perpetual inventory record for any specified period of time and shall state the current inventory quantities of each drug at the time the record is printed. An electronic record entry, once recorded, shall not be changed; any needed adjustments or corrections shall require entry of a separate record as provided in subrule 11.29(3).

11.29(2) *Information included.* The perpetual inventory record shall identify all receipts and disbursements of Schedule II controlled substances by drug name or by National Drug Code (NDC), including each patient administration, wastage, return to the responsible individual, disposal of a drug, and a receipt of each drug. The record of receipt shall also identify the source of the drug, the strength and dosage form, the quantity, the date, and the name or unique identification of the individual verifying receipt of the drug. The disbursement record shall identify where or to whom the drug is disbursed or

administered, the strength and dosage form, the quantity, the date, and the name or unique identification of the individual responsible for the disbursement.

11.29(3) *Changes to the record.* Any changes or adjustments made to the perpetual inventory shall include the identity of the person making the change and the reason for the change or adjustment.

11.29(4) *Reconciliation.* The pharmacist in charge or designee in a pharmacy-based program, or the medical director or designee in a medical director-based program, shall be responsible for reconciling the physical inventory of all Schedule II controlled substances with the perpetual inventory balance on a periodic basis but no less frequently than monthly. Any discrepancy shall be reported to the medical director and to the pharmacist in charge if the service program is a pharmacy-based program.

657—11.30(124,147A,155A) Controlled substances annual inventory. An accurate inventory shall be taken annually of all controlled substances maintained at the service program site. Controlled substances in a pharmacy-based program shall be included in the pharmacy's annual controlled substance inventory. Records of the inventory shall be maintained pursuant to rule 657—11.34(124,147A,155A).

657—11.31 Reserved.

657—11.32(124,147A,155A) Destruction or disposal of controlled substances. Disposal or destruction of controlled substances shall be pursuant to the requirements of this rule and rule 657—11.29(124,147A,155A). Records shall be maintained at the service program site and, if the program is a pharmacy-based service, records shall be maintained at both the service program site and the pharmacy.

11.32(1) *Outdated, damaged, or unwanted supply.* EMS personnel shall not destroy any controlled substances except as provided in subrule 11.32(2). Any drug that requires disposal or destruction shall be returned to the responsible individual. The responsible individual shall dispose of or destroy controlled substances according to the following procedures:

a. The responsible individual shall utilize the services of a DEA-registered and Iowa-licensed disposal firm (reverse distributor), or

b. The responsible individual shall utilize such other means determined and approved by the board.

11.32(2) *Administration wastage.* Except as otherwise specifically provided by federal or state law or rules of the board, the unused portion of a controlled substance resulting from administration to a patient may be destroyed or otherwise disposed of by the administering EMS personnel, the medical director, or a pharmacist. Any wastage of a controlled substance shall be conducted in the presence of a responsible adult witness who is a member of the EMS team. A written record of controlled substance wastage shall be made and maintained at the service program location and at the pharmacy, if the program is a pharmacy-based service, for a minimum of two years following the destruction or other disposal. The record shall include the signatures of the individual destroying or otherwise disposing of the wastage of the controlled substance and of the witness and shall identify the following:

a. The controlled substance wasted;

b. The date of destruction or other disposition;

c. The quantity or estimated quantity of the wasted controlled substance;

d. The source of the controlled substance, including identification of the patient to whom the substance was administered; and

e. The legibly printed names of the person wasting the unused portions of the controlled substance and of the qualified witness.

657—11.33(124,147A,155A) Report of loss or theft of controlled substance. Upon suspicion of any loss or theft of a controlled substance, the service director shall immediately notify the responsible individual. The responsible individual shall notify the DEA pursuant to rule 657—10.16(124) and federal regulations. The responsible individual shall report in writing, on forms provided by the board, any theft or significant loss of any controlled substance. The report shall be submitted to the board office within

two weeks of the discovery of the theft or loss. A copy of the report shall be maintained at the service program site and, if the program is a pharmacy-based service, at the pharmacy.

657—11.34(124,147A,155A) Records. All records regarding prescription drugs and devices in a service program shall be maintained for two years and be available for inspection and copying by the board or its representative.

These rules are intended to implement Iowa Code chapter 147A and Iowa Code sections 124.301 and 155A.13.